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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/416,267	10/12/1999	KUI SU	PF270P1	5938
22195	7590	02/04/2004	EXAMINER	
HUMAN GENOME SCIENCES INC 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850			MERTZ, PREMA MARIA	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 02/04/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/416,267

Applicant(s)

SU ET AL.

Examiner

Prema M Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-24 have been canceled previously. Claims 25-79 are under consideration.
2. Receipt of applicant's arguments filed on 11/24/2003 is acknowledged.
3. Applicant's arguments filed on 11/24/2003 have been fully considered but were non-persuasive. The issues remaining are stated below.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101, 112 first paragraph

5. Claims 25-79 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

This rejection is maintained for reasons of record set forth at pages 2-8 of the previous Office action (7/10/2003), 3-5 of the previous Office action (9/7/00), pages 2-6 of the previous Office action (5/3/01), pages 2-8 of the previous Office action (9/16/02) and pages 2-5 of the previous Office action (2/10/03).

Applicants argue that the polypeptides of the invention do indeed have a determined function and biological significance and have again cited Graf et al for this proposition. Graf et al (2002) published six years after the earliest filing date of the instant application, demonstrate that the polypeptides of the present invention are expressed and play a role in the regulated development of T cells in the thymus. There is absolutely n support in the Graf et al publication that the polypeptides of the instant invention may be used to treat inflammation. All that is recited in the instant invention is the assertion that the polypeptides of the present invention may

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be used to treat inflammation (see page 3, lines 5-8 of the instant specification). This is not a specific and substantial utility for the reasons recited below.

Applicants argue that inflammation is a process, which is dependent on T-cell maturation and activation. Applicants have redirected the Examiner's attention to Janeway and Travers for the premise that inflammation as a result of the inflammatory response occurs when a tissue is exposed to any one of a number of noxious stimuli including, for example, bacterial infections. The first cells involved in the inflammatory response are non-specific "inflammatory cells" such as monocytes and neutrophils; however, there may be later recruitment and activation of T cells in chronic inflammation. Therefore, T cells may play a role in inflammation and this activity of T cells is one of the possible functions of T cells out of a variety of possible T cell functions. Therefore, contrary to Applicants arguments, it is not widely appreciated in the art that recruitment and activation of T cells is a necessary and specific step in the inflammatory process.

Furthermore, inflammation is a time specific response and T cells may be attracted to the area but may have absolutely no effect on the inflammatory response. As stated earlier, there are several functions biological functions of T cells and participation of the inflammation may be one of them but it is not a requirement for T cells to be involved in inflammation. Applicants have set forth a speculative utility for the instantly claimed protein, the utility not being in a readily useful form at the time of the instant invention. Applicants are reminded that "Argument of counsel cannot take the place of evidence lacking in the record" (*In re Scarbrough*, 182 USPQ 298, 302 (CCPA 1974)).

Applicants argue that maturation and selection of T cells occurs in the thymus and continues into adult life and have cited the Abbas et al. reference in this regard. However, the

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issue here is that the fact that T-cell development occurs in the thymus and continues into adult life is irrelevant to the patentability of the instant claims. The issue here is not that the instant protein is not a cytokine but that at the time of filing of the instant application would there have been a correlation between the biological activity of the instant protein and the asserted utility? The instant specification provides no guidance as to how to direct efforts to use the instant protein in the recited vague uses. Given that the involvement of T cells in the inflammatory process is not the cause of inflammation, the assertion originally made by Applicants regarding the involvement of the instant protein in inflammation is not a specific and substantial utility.

Claims 25-79 are also rejected under 35 U.S.C. 1 12, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification fails to disclose a specific and substantial asserted utility or well established for the claimed protein. The fact that the claimed protein has about 30% homology to the Tsg protein is not sufficient to establish a specific and substantially asserted utility or a well established utility for it.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

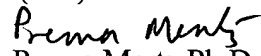
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Prema Mertz Ph.D.
Primary Examiner
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December 18, 2003